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No. OFFICE OF THE CLERK

In The

Supreme Court of the United States

October Term, 1996

KANDIS L. PAPIKE,

Petitioner,

vs.

TAMBRANDS, INC.,

Respondent.

Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

PETITION FOR WRIT OF CERTIORARI

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179 pp

QUESTIONS PRESENTED

Whether the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"), specifically 21 U.S.C.S. § 360(k) and the corresponding regulations promulgated by the Food and Drug Administration ("FDA"), pre-empts Petitioner's state law claims based on failure to adequately warn about the relationship between the use of the Respondent's tampon product and Toxic Shock Syndrome.

Whether factual questions exist concerning the Respondent's compliance with the labeling requirements of FDCA in the labeling of their tampon packaging concerning Toxic Shock Syndrome, specifically 21 U.S.C.S. § 352, and the corresponding regulations promulgated by the FDA.

Whether the Court of Appeals erred in failing to view the evidence in the light most favorable to the Petitioner.

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Petitioner Kandis L. Papike ("Kandis") respectfully requests that a writ of certiorari be issued to review the judgment of the United States Court of Appeals for the Ninth Circuit in this case as that court has decided important questions of federal law in a way that conflicts with this Court's decision in *Medtronic Inc. v. Lohr*, 116 S. Ct. 2240 (1996).

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Ninth Circuit is reported at *Papike v. Tambrands, Inc.*, 107 F.3d 737 (9th Cir. 1997) (App. A). The opinions of the district court in *Papike v. Tambrands, Inc.*, D.C. No. CV-93-05114-WJR are not published (App. B, C, D, E).

STATEMENT OF JURISDICTION

The judgment of the United States Court of Appeals for the Ninth Circuit ("Court of Appeals") was entered on February 20, 1997. The Court of Appeals denied a timely petition for rehearing on April 16, 1997 (App. F).

The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTES AND REGULATION INVOLVED

21 U.S.C.S. § 360(k) provides in relevant part:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement —
>
> (1) which is different from, or in

> addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 C.F.R. § 808.1(d) provides in relevant part:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. ***There are other State or local requirements that affect devices that are not preempted by [21 U.S.C. §360(k)] because they are not "requirements applicable to a device" within the meaning of [21 U.S.C. §360(k)].*** The following are examples of State or local requirements that are not regarded as preempted by [21 U.S.C. §360(k)]:
>
> (1) **[21 U.S.C. §360(k)] does not preempt State or local requirements of general applicability where the purpose of the requirement relates**

> **either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.**

(Emphasis supplied).

21 U.S.C.S. § 352 provides in relevant part:

> A drug or device shall deemed to be misbranded —
>
> > (c) If any word, statement, or other information required by or under authority of this Act to appear on the label . . . is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

21 C.F.R. § 801.15(a) provides in relevant part:

> A word, statement, or other information required by or under authority of the act to appear on the label may lack that prominence and conspicuousness required by [21 USCS §352] by reason, among other reasons, of:

(1) The failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(2) The failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

* * *

(4) Insufficiency of label space for the prominent placing of such word, statement, or information, resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;

(5) Insufficiency of label space for the placing of such word, statement, or information, resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device;

(6) Smallness or style of type in

which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

STATEMENT OF THE CASE

Kandis filed a lawsuit in the United States District Court of California, Central Division, against the Respondent ("Tambrands") to recover for injuries that she sustained after she developed Toxic Shock Syndrome ("TSS") in October of 1992 as a result of using tampons designed, manufactured and distributed by Tambrands. The district court has jurisdiction over this civil suit by virtue of 28 U.S.C. § 1332.

In motions for summary judgment, Tambrands contended that Kandis' state law based failure to warn claims were pre-empted the FDCA and associated regulations; that her design defect claim failed the "consumer expectation" and "risk-benefit" tests under California law; and that her claims of negligence, breach of warranties, and for punitive damages could not be sustained because the consumer expectation test is synonymous with the "reasonableness" test in a negligence action. The district court sustained the motions for summary judgment and eventually dismissed Kandis' case. Kandis moved the district court to reconsider its ruling on the motion for partial summary judgment related to the design defect claim and that motion was denied on January 20, 1995. Kandis timely appealed.

The Ninth Circuit affirmed the district court's ruling on the preemption issue relying primarily on this Court's decision in *Medtronic Inc. v. Lohr*, 116 S. Ct. 2240 (1996). The Ninth Circuit held that, as a matter of law, Tambrands complied with

21 U.S.C. § 352 requirements of prominence of the labeling information.

Kandis' petition for rehearing with suggestion for rehearing en banc was denied.

REASONS FOR GRANTING THE WRIT

I.

THE COURT OF APPEALS DECISION IS IN CONFLICT WITH THIS COURT'S DECISION IN *MEDTRONIC INC. v. LOHR*, AND, AS A RESULT, IMPORTANT FEDERAL QUESTIONS RELATING TO THE PREEMPTIVE EFFECT OF THE FDCA HAVE BEEN DECIDED INCORRECTLY.

Pursuant to its authority granted to it under the FDCA, the FDA has promulgated a regulation requiring that certain "consumer information" be placed on or in tampon packaging. 21 C.F.R. § 801.430. The FDA's stated purpose for requiring the consumer information is to "[t]o protect the public and to minimize the serious adverse effects of TSS." 21 C.F.R. § 801.430(b). With respect to this consumer information, the FDA allows Tambrands to develop their own wording provided that certain topics are addressed. 47 Fed. Reg. 26989 (1982). The FDA provided this flexibility in order to obligate Tambrands to add additional consumer information about TSS when it becomes available. *Id.*

The Court of Appeals, relying on its interpretation of this Court's holding in *Medtronic Inc. v. Lohr*, 116 S. Ct. 2240 (1996), held that "[p]reemption results in [Kandis'] case because the FDA has established specific counterpart regulations with respect to labeling tampons" and therefore 21 USCS § 360(k)

preempts her state common law claim based on failure to adequately warn. *Papike v. Tambrands*, 107 F.3d 737, 741 (1997).

The Court of Appeals erred, as the FDA regulations relating to tampon labeling are too general to warrant preemption. *See*: 21 C.F.R. § 808.1(d); *Accord*, *Medtronic*, 116 S. Ct. 2240 (1996). Additionally, Kandis' state based failure to warn claim is not preempted because it is possible for Tambrands to comply with both the FDA regulations and any state common law requirements which relate to tampon labeling; and as the FDA has given Tambrands broad latitude in the wording, style and placement of the consumer information, the FDA has left room for the States to supplement FDA regulations. *Medtronic*, 116 S. Ct. at 2261 (Breyer, J., concurring in part).

Medtronic, was a plurality opinion authored by Justice Stevens who was joined by Justices Kennedy, Souter and Ginsburg. Justice Breyer wrote a separate opinion in which he joined in five of seven parts of Justice Stevens' opinion. The five parts in which he joined were one, two, three, five and seven. Those five parts constitute the decision of this Court.

In part five of *Medtronic*, this Court recognized the FDA's "unique role in determining the scope of the [FDCA's] preemptive effect." 116 S. Ct. 2255. The Court then acknowledged that the FDA interprets 21 U.S.C.S. § 360(k) as not preempting state or local requirements of general applicability where the purpose of the requirements relate to other products in addition to devices. 116 S. Ct. at 2257. As general state common law requirements have not been developed specifically with respect to medical devices, this Court concluded that common law requirements are not the kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal

requirements. 116 S. Ct. at 2258. Claims based on failure to adequately warn, are based upon a type of general obligation which escapes preemption because its generality leaves it outside the category of requirements that the MDA envisioned to be "with respect to" medical devices. *Id.*

In part three of *Medtronic*, the majority acknowledged that Congress has "not cavalierly pre-empt[ed] state-law causes of action. 116 S. Ct. at 2250. Additionally, an inquiry into congressional purpose for the legislation must be made. *Id.* Justice Breyer, in his concurring opinion, notes that a federal requirement will only preempt a state requirement if: (1) compliance with both the federal requirement and the state requirement is impossible; or (2) Congress has left no room for the states to supplement the scheme of federal regulation. 116 S. Ct. at 2261.

As the FDA's labeling regulations allow tampon manufacturers broad latitude in the wording, style and placement of the consumer information, and since the regulations do not specify that the required topics are the exclusive topics to be addressed, the FDA regulations cannot stand as a preemptive barrier to Plaintiffs' state common law based failure to warn claim.

II.

CONTRARY TO THE JUDGMENT OF THE COURT OF APPEALS, FACTUAL QUESTIONS EXIST IN THIS CASE, FOR THE TRIER OF FACT TO DETERMINE, AS TO WHETHER TAMBRANDS HAS COMPLIED WITH THE LABELING REQUIREMENTS OF THE FDCA, SPECIFICALLY 21 U.S.C.S. § 352, AND THE CORRESPONDING REGULATIONS PROMULGATED BY THE FDA.

The Court of Appeals ruled that Tambrands' warnings complied with the tampon labeling regulations. In so doing, the Court of Appeals ignored Kandis' argument that Tambrands failed to comply with 21 C.F.R. § 801.15(a). Specifically, Kandis is prepared to show at trial that Tambrands has not put the alert statement on the "panel of the label which is presented or displayed under customary conditions of purchase" (a violation of 21 C.F.R. § 801.15(a)(1)); that Tambrands has failed to put the alert statement on two or more parts of the panels of the label so designed as to render it to be, under customary conditions of purchase, likely to be displayed (a violation of 21 C.F.R. § 801.15(a)(2)); that Tambrands has failed to devote sufficient label space to the alert statement, when compared to other designs on the labeling (a violation of 21 C.F.R. § 801.15(a)(3) and (4)); and that Tambrands has provided the alert statement with insufficient background contrast and that the alert statement is crowded by other written and graphic matter (a violation of 21 C.F.R. § 801.15(a)(5)).

Furthermore, the Court of Appeals ignored the fact that Tambrands has failed to update the consumer information as contemplated by 47 Fed. Reg. 26989 (1982). The Court of Appeals ruled that it was sufficient for Tambrands to "track the language of §801.430(d) almost verbatim." *Papike v.*

Tambrands, Inc., at 743. Kandis is prepared to show that Tambrands is obligated under the regulations of the FDA to provide additional consumer information by way of alerting women that despite years of prior safe tampon use, that they are still at risk for TSS; that scientific studies have determined that all-cotton tampons are the safest tampons since cotton does not amplify toxin production; that Tampax tampons have been demonstrated to be associated with an increased risk of TSS; and that tampons are still associated with TSS despite the fact that Proctor & Gamble's Rely tampon was forced off the market by the FDA.

III.

THE COURT OF APPEALS ERRED IN FAILING TO VIEW THE EVIDENCE IN THE LIGHT MOST FAVORABLE TO KANDIS.

This Court has consistently held that "at the summary judgment stage the judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 106 S. Ct. 2505, 2510 (1986). This Court has held that:

> Credibility determinations, the weighing of the evidence and the drawing of legitimate inferences from the facts are jury functions, not those of the judge whether he is ruling on a motion for summary judgment or for a directed verdict. The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor.

106 S. Ct. at 2513.

Kandis is prepared to demonstrate at trial that rayon, which Tambrands utilizes in the manufacture of the tampon used by Kandis when she became ill, is an inappropriate fiber. Kandis is prepared to call Dr. Philip Tierno, a microbiologist who has conducted tampon/ TSS testing, to establish the design defect. The Court of Appeals invaded the province of the jury in ruling that the Tierno affidavit was insufficient to establish a design defect. *Papike* at 743. Dr. Tierno's research has clearly demonstrated that rayon containing tampons are defective in that they amplify toxin production.

CONCLUSION

For the foregoing reasons, the petition for writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT FILED FEBRUARY 20, 1997

FOR PUBLICATION

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

KANDIS L. PAPIKE,
Plaintiff-Appellant,
v.
TAMBRANDS INC.,
Defendant-Appellee.

No. 95-55173
D.C. No. CV-93-05114-WJR
OPINION

Appeal from the United States District Court
for the Central District of California
William J. Rea, District Judge, Presiding

Argued and Submitted
October 8, 1996—Pasadena, California
Filed February 20, 1997

Before: Diarmuid F. O'Scannlain, Thomas G. Nelson and Michael Daly Hawkins, Circuit Judges.

Opinion by Judge T.G. Nelson

SUMMARY

Torts/Products Liability

The court of appeals affirmed a judgment of the district court. The court held that a state tort law failure-to-warn claim based on a consumer's injuries from using a tampon is preempted by the Medical Devices Amendments (MDA) to the Food, Drug and Cosmetics Act (FDCA).

Appendix A

Appellant Kandis Papike brought a products liability action against appellee Tambrands, Inc. for injuries she sustained when she contracted toxic shock syndrome (TSS) while using Tampax tampons. The complaint alleged that the tampons were defective because they contained viscose rayon; that Tambrands failed adequately to warn her about an established association between Tampax tampons and TSS; and that Tambrands failed to comply with federal regulations governing TSS warnings.

In motions for summary judgment, Tambrands contended that the MDA and associated regulations preempted Papike's failure-to-warn claim; that her design defect claim failed the "consumer expectation" and "risk-benefit" tests under California law; and that her claims of negligence, breach of warranties, and for punitive damages could not be sustained because the consumer expectations test is synonymous with the "reasonableness" test in negligence actions.

The MDA's preemption section provides that state law may not impose any "requirement" with respect to a medical device that is "different from" or "in addition to" the statute's requirements, and that relates to the safety or effectiveness of the device, or to any other matter included in any applicable requirement of the MDA.

Papike asserted that the tampon labeling regulation is too general to support preemption because it allows manufacturers broad latitude in the wording, style, and placement of consumer information. On her design defect claim, Papike submitted the affidavit of Dr. Tierno, a microbiologist who had performed TSS-related testing on tampons.

The FDA's tampon-labeling regulation specifies the consumer information that must appear on the product's box or in a package insert, including statements on the risk and warning signs of TSS, steps for avoiding the risk, and actions the user should take if symptoms appear.

Appendix A

The Food and Drug Administration (FDA) interprets the MDA's preemption provision as providing that state labeling requirements are preempted when the FDA has established specific counterpart regulations, or there are other specific requirements applicable to a particular device under the FDCA.

The district court granted Tambrands' summary judgment motions. The court concluded that Tambrands' warnings were sufficient under federal law; that Papike's failure to meet the "consumer expectation" and "risk-benefits" tests defeated her design defect and negligence claims; and that Tierno's affidavit was insufficient to avoid summary judgment because his test results did not establish a causal connection between the Tampax tampons and TSS. Papike appealed.

[1] The FDA has broad powers under the MDA to regulate medical devices. Tampons are Class II medical devices under the MDA. Use of Class II medical devices involves some risk of injury, so manufacturers must comply with regulations concerning tampon labeling.

[2] The FDA promulgated a regulation mandating the content of the TSS warnings on tampon boxes and/or package inserts. The regulation is not only device-specific (tampons), but also disease-specific (TSS). [3] Although the regulation provides some flexibility to the manufacturer, it mandates the specific substantive content of the TSS warning. Preemption resulted in this case because the FDA established specific counterpart regulations with respect to labeling tampons. [4] That the state "requirement" arose out of a state common-law cause of action for failure to warn, rather than from a state statute, did not save Papike's claim from preemption.

[5] Tambrands' warnings complied with the tampon labeling regulation, including the prominence requirement. The package insert tracked the language of the regulation almost

verbatim, and conveyed to the consumer everything the regulations require the manufacturer to explain.

[6] Under California law, a product is defectively designed if it fails to meet an ordinary consumer's expectations, or if injury is attributable to a specific design feature and the risks associated with the design outweigh its benefits. [7] Tambrands' warnings met federal requirements. Papike's design defect claim therefore failed the "consumer expectation" test.

[8] The district court's rejection of the Tierno affidavit was not an invasion of the province of the jury, but part of the court's duty to evaluate Papike's showing of the existence of some significant probative evidence.

[9] Because the "consumer expectation" strict liability test is synonymous with the "reasonableness" test in negligence claims, Papike's negligent design claim also failed. [10] The legally adequate warnings, which gave notice to consumers of the possibility of contracting TSS, foreclosed Papike's claims for breach of warranty. The claim for punitive damages failed as well.

COUNSEL

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Roger E. Podesta, Debevoise & Plimpton, New York, New York, for the defendant-appellee.

OPINION

T.G. NELSON, Circuit Judge:

Kandis Papike appeals from the district court's summary judgment dismissal of her diversity products liability action

against Tambrands Inc. for injuries she sustained when she contracted Toxic Shock Syndrome ("TSS") while using Tampax Original Regular tampons. The primary issue on appeal is whether Papike's state law claim for failure to warn of the risk of TSS related to tampon use is preempted by the Medical Devices Amendments of 1976 ("MDA"), 90 Stat. 539 (codified as amended at 21 U.S.C. §§ 360, 360c-360*l* (Supp. 1996)). We hold that the claim is preempted. We also hold that the district court properly concluded that Tambrands' warnings complied with federal requirements, and properly dismissed the design defect, negligence, breach of warranty, and punitive damages claims. We affirm the grant of summary judgment to Tambrands.

I

In this action Papike contends, *inter alia*, that Tampax tampons are defective because they contain viscose rayon; that Tambrands failed to adequately warn her about an established association between Tampax tampons and TSS; and failed to comply with federal requirements for TSS warnings. Papike's action was dismissed through a series of summary judgment rulings.

The district court agreed with Tambrands that "any state law causes of action for failure to warn are preempted by the comprehensive federal regulatory scheme covering tampons and TSS." The court found Tambrands' warnings, "which track the language of the federal regulations almost verbatim, constitute sufficient warning as a matter of law."

The design defect claim was later dismissed because it failed both the "consumer expectation" test and the "risk benefit" test under California law. The court concluded that the affidavit of Dr. Tierno, a microbiologist who has conducted TSS-related testing of tampons, failed to raise an issue of triable fact concerning a causal connection between Tampax Original Regular tampons and TSS.

The court later dismissed the complaint when it granted Tambrands' summary judgment motion on the remaining claims of negligence, breach of express and implied warranties, and punitive damages. The court denied Papike's motion for reconsideration, and she timely appeals. The district court had diversity jurisdiction under 28 U.S.C. § 1332. We have jurisdiction under 28 U.S.C. § 1291.

II

Our review of the district court's summary judgment order is *de novo*. *Bagdadi v. Nazar*, 84 F.3d 1194, 1197 (9th Cir. 1996). In reviewing the court's order we must view the evidence in the light most favorable to Papike and determine whether there are any genuine issues of material fact and whether the court correctly applied the relevant substantive law. *Id.*

III

We first consider whether the preemption provision of the Medical Devices Amendments to the federal Food, Drug & Cosmetics Act, 21 U.S.C. § 360k(a), and the tampon labeling regulations promulgated thereunder, 21 C.F.R. § 801.430, preempt state tort law claims for failure to warn.

A

[1] The Food and Drug Administration ("FDA") has broad powers under the MDA to classify and regulate medical devices. *See* 21 U.S.C. § 360c(b)-(f); 21 U.S.C. § 371(a). Tampons are "Class II" medical devices under the MDA. 21 C.F.R. §§ 884.5460, 884.5470 (1996). Use of Class II devices involves some risk of injury, so manufacturers of these devices must comply with federal regulations known as "special controls." 21 U.S.C. § 360c(a)(1)(B) (Supp. 1996); 21 C.F.R. § 860.3(c)(2) (1996). The FDA has promulgated regulations concerning tampon labeling "[t]o protect the pub-

lic and to minimize the serious adverse effects of TSS." 21 C.F.R. § 801.430(b). For example, a tampon manufacturer must label tampons with

> the following consumer information prominently and legibly, in such terms as to render the information likely to be read and understood by the ordinary individual under customary conditions of purchase and use:
>
> (1)(i) Warning signs of TSS, e.g., sudden fever (usually 102 [degrees] or more) and vomiting, diarrhea, fainting or near fainting when standing up, dizziness, or a rash that looks like a sunburn;
>
> (ii) What to do if these or other signs of TSS appear, including the need to remove the tampon at once and seek medical attention immediately;
>
> (2) The risk of TSS to all women using tampons during their menstrual period, especially the reported higher risks to women under 30 years of age and teenage girls, the estimated incidence of TSS of 1 to 17 per 100,000 menstruating women and girls per year, and the risk of death from contracting TSS;
>
> (3) The advisability of using tampons with the minimum absorbency needed to control menstrual flow in order to reduce the risk of contracting TSS;
>
> (4) Avoiding the risk of getting tampon-associated TSS by not using tampons, and reducing the risk of getting TSS by alternating tampon use with sanitary napkin use during menstrual periods; and

> (5) The need to seek medical attention before again using tampons if TSS warning signs have occurred in the past, or if women have any questions about TSS or tampon use.

21 C.F.R. § 801.430(d). If this information is included as a package insert (rather than on the tampon box), an alert statement must be "prominently and legibly" placed on the package label:

> ATTENTION: Tampons are associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and save the enclosed information.

21 C.F.R. § 801.430(c).

The MDA contains an express, but "highly ambiguous" provision for the preemption of state law. *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240, 2260 (1996) (Breyer, J., concurring in part and concurring in the judgment), which provides that:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use *any requirement*—
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (1984) (emphasis added).

The FDA interprets this preemption provision in 21 C.F.R. § 808.1(d), which provides that:

> State or local requirements are preempted *only* when the Food and Drug Administration has established *specific* counterpart regulations or there are other *specific* requirements applicable to a *particular* device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the *specific* Food and Drug Administration requirements.

21 C.F.R. § 808.1(d) (1996) (emphasis added). Section 808.1(d)(1) provides that "State or local requirements of *general applicability*" are not preempted

> where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

21 C.F.R. § 808.1(d)(1) (1996) (emphasis added).

The Supreme Court "[has] long presumed that Congress does not cavalierly pre-empt state-law causes of action." *Medtronic*, 116 S. Ct. at 2250. "The purpose of Congress is the ultimate touchstone" in a preemption case. *Retail Clerks Int'l Ass'n v. Schermerhorn*, 375 U.S. 96, 103 (1963).

B

[2] In this case, the FDA has promulgated a regulation mandating the specific substantive content of the TSS warnings on tampon boxes and/or tampon package inserts. 21 C.F.R. § 801.430. The regulation is not only device-specific (tampons), but also disease-specific (TSS). This fact distinguishes Papike's case from prior relevant MDA preemption cases, including *Medtronic*, 116 S. Ct. at 2258 (general fed-

eral labeling and manufacturing requirements reflecting "important but entirely generic concerns about device regulation generally," not pacemakers specifically); *Committee of Dental Amalgam Mfrs. and Distribs. v. Stratton*, 92 F.3d 807, 812-13 (9th Cir. 1996) (no specific FDA regulations relating to dental amalgam), *cert. denied*, ___ S. Ct. ___, 65 U.S.L.W. 3486 (1997); *Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1459 (9th Cir. 1995) (premarket approval process for Class III devices is not a " '*specific* requirement applicable to a *particular* device' "), *cert. denied*, 116 S. Ct. 2579 (1996); and *Anguiano v. E.I. Du Pont De Nemours & Co.*, 44 F.3d 806, 809-10 (9th Cir. 1995) (no specific FDA regulations regarding carbon material used in jaw implants).

In *Medtronic*, a divided Supreme Court addressed the extent to which state common-law claims of negligence and strict liability against the manufacturer of a failed pacemaker were preempted. 116 S. Ct. at 2248, 2250. Significantly, the manufacturer contended that the plaintiff's claims were preempted by the FDA's "general 'good manufacturing practices' regulations, which establish general requirements for most steps in every device's manufacture, and by the FDA labeling regulations, which require devices to bear various warnings." *Id.* at 2249 (citations omitted). The Supreme Court unanimously held that the plaintiff's state common-law claim for defective design of a Class III pacemaker was not preempted by the MDA. The Court split five to four in holding that the plaintiff's negligent manufacturing and inadequate labeling claims were also not preempted. The plurality decision was authored by Justice Stevens (joined in by Justices Kennedy, Souter, and Ginsburg). Justice Breyer wrote a separate opinion (concurring in part and concurring in the judgment), in which he joined in five of the seven parts of Justice Stevens' opinion. Justice O'Connor, joined by the Chief Justice and Justices Scalia and Thomas, concurred in part and dissented in part.

The Justices were unanimous in *Medtronic* in holding that there can be no preemption under the MDA unless there is an

FDA regulation that is in some manner applicable to the device. *Id.* at 2254-55, 2257 (majority opinion); *id.* at 2261 (Breyer. J., concurring in part); *id.* at 2264 (O'Connor, J., concurring in part and dissenting in part); *see also id.* at 2252 n.9 ("In the MDA, no such specifics exist until the FDA provides them."). We have previously held that "the scope of preemption is limited to instances where there are specific FDA requirements applicable to a particular device." *Anguiano*, 44 F.3d at 809 (internal quotation omitted); *see also Committee of Dental Amalgam*, 92 F.3d at 812.

Unlike the general federal requirements in *Medtronic*, the warning requirements here reflect "the sort of concerns regarding a specific device or field of device regulation which the . . . regulations were designed to protect from potentially contradictory state requirements." *See Medtronic*, 116 S. Ct. at 2258. This, then, *is* a case "in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers." *Id.*

[3] Papike contends that the tampon labeling regulation is too general to warrant preemption because it allows tampon manufacturers "broad latitude in the wording, style, and placement of the consumer information." We disagree. Although the regulation provides some flexibility to the manufacturer, it mandates the specific substantive content of the TSS warning. Preemption results in this case because the FDA has established specific counterpart regulations with respect to labeling tampons. *See* 21 C.F.R. § 808.1(d). *Accord, Medtronic*, 116 S. Ct. at 2254-55, 2257 (majority opinion); *id.* at 2261 (Breyer, J., concurring in part); *id.* at 2264 (O'Connor, J., concurring in part); *Anguiano*, 44 F.3d at 810.

[4] That the state "requirement" in this case arises out of a state common-law cause of action for failure to warn, rather than a specific state statute, does not save Papike's claim from preemption. The plurality in *Medtronic* stops short of declaring that common law duties are never "requirements" under § 360k, finding it unnecessary to reach this issue. *Id.* at 2258-59. Five Justices did, however, conclude that "requirement" encompasses state common-law claims to the extent that their recognition would impose any requirements different from, or in addition to, FDA requirements applicable to the device. *Id.* at 2259-60 (Breyer, J., concurring in part); *id.* at 2262, 2263, 2264 (O'Connor, J., joined by three other Justices, concurring in part). A majority of the Court has spoken on this issue, and to the extent we concluded in *Kennedy* that the MDA cannot preempt *any* state common-law causes of action, the conclusion cannot survive in light of the concurring and dissenting opinions in *Medtronic*. *See Marks v. United States*, 430 U.S. 188, 193-94 (1977).

We must next consider whether Papike's warning claim is saved from preemption because it arises under "generally applicable" principles of state tort law. *See* 21 C.F.R. § 808.1(d)(1). Papike contends that we must look not only at the specificity of the federal requirements, but also at whether or not the state law being preempted was "specifically developed 'with respect to' medical devices." *See Medtronic*, 116 S. Ct. at 2258 (Part V of Justice Stevens' plurality decision, joined in by Justice Breyer). She argues that preemption cannot be triggered in this case because a common law tort rule of general applicability is not a state requirement that is made "with respect to" a medical device. Papike relies on Section V of Justice Steven's opinion in which the Court concluded that the plaintiff's defective manufacturing and labeling claims, which are based on general duties owed to consumers,

> escape pre-emption, not because the source of the duty is a judge-made common-law rule, but because their generality leaves them outside the category of

> requirements that § 360k envisioned to be "with respect to" specific devices such as pacemakers.

Id.

Although Justice Breyer joined in Section V, a fair reading of that Section and of Justice Breyer's separate opinion does not support Papike's claim that tampon manufacturers must comply both with FDA labeling requirements and state common-law labeling duties. In Section V, the Court evaluates the specificity of the general state common-law requirements, but only after concluding that the federal labeling and manufacturing requirements at issue were not specific to pacemakers. *Id.*; *see also id.* at 2261 (Breyer, J., concurring in part) ("Insofar as there are any applicable FDA requirements here, those requirements, even if numerous, are not 'specific' in any relevant sense."). Although *Medtronic* was described by Justice O'Connor as "bewildering and seemingly without guiding principle," *id.* at 2262, it is clear enough that the Court found no preemption of the common-law claims largely because the pacemaker was not subject to any device-specific FDA regulations. In addition, Section V acknowledges that the statutory and regulatory preemption language does not necessarily preclude " 'general' state requirements from ever being pre-empted." *Id.* at 2257; *see also id.* at 2263 (O'Connor, J.) (pointing out confusion created in Sections IV, V, and VI of the plurality opinion).

As counsel for Tambrands pointed out at oral argument, it makes little sense to argue that Justice Breyer would write separately to make clear his position that duties arising under state common law can constitute state law "requirements" which can be preempted by the MDA, and then agree that because tort law consists of generally applicable principles, it is always preempted, even in the face of specific federal requirements. Instead, in *Medtronic* Justice Breyer found "no actual conflict between any federal requirement and any of the liability-creating-premises of the plaintiffs' state law tort

suit." *Id.* at 2261. Here, there would be such a conflict. Part of Papike's claim is that the federal requirements do not suffice, and that Tambrands should be required to, among other things, add a variety of warning statements not required by the federal regulation. As Justice Breyer explained, these are "the legal requirements that grow out of the application, in particular circumstances, of a State's tort law." *Id.* at 2259. Papike alleges generally applicable state law principles are involved, but there is a specific FDA regulation to which the generally applicable principles would be imposing additional or different requirements. *See also* 21 C.F.R. § 808.1(d)(6)(ii) ("Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act.").

In summary, preemption is triggered by and "the scope of preemption is limited to instances where there are specific FDA requirements applicable to a particular device." *Anguiano*, 44 F.3d at 809 (internal quotation omitted). The tampon labeling regulation is device- and disease-specific and preemption is warranted in this case. This result is entirely consistent with *Medtronic*, which did not involve device-specific federal requirements. *Kennedy* does not support Papike's position because not only did it involve general federal requirements, but also because its conclusion that a common-law claim cannot be preempted does not survive the five Justices' contrary conclusion in *Medtronic*. We need not address Papike's alternative arguments.

IV

We next consider Papike's claim that the district court erred when it concluded that Tambrands' warnings were sufficient under federal law. She contends that a jury could find that the warnings here violated 21 U.S.C. § 352(c) (general misbranding statute addressing prominence of label informa-

tion), 21 C.F.R. § 801.15(a) (general regulation addressing prominence of label statements on medical devices), and the specific tampon labeling regulation, 21 C.F.R. § 801.430.

[5] We find no error. First, Tambrands' warnings comply with the tampon labeling regulation. The alert statement on the package complies with § 801.430(c), including the prominence requirement. *See Lindquist v. Tambrands, Inc.*, 721 F. Supp. 1058, 1064-65 (D. Minn. 1989) ("As mandated by 21 C.F.R. § 801.430(c), the tampon package includes an alert statement worded precisely as required by the regulation and in a typeface separate and readily distinguishable from other text appearing on the panel."). The package insert tracks the language of § 801.430(d) almost verbatim, and certainly conveys to the consumer everything the regulations require the manufacturer to explain.

Second, arguing that the more general statute and regulation on "prominence" of medical device warnings could require something else or something additional does not create a material issue of fact sufficient to preclude summary judgment in the face of compliance with the specific tampon labeling requirements. *See, e.g., Beecher v. Tambrands, Inc.*, 840 F. Supp. 86, 87-88 (D. Minn. 1993). Tambrands' warnings were sufficient under federal law.

V

[6] We next consider Papike's argument that the district court erred in dismissing her design defect claim. She contends that the Tampax Original Regular tampon was defectively designed because it contains a layer of viscose rayon, which she alleges amplifies toxin production. Under California law, a product is defectively designed if it fails to meet an ordinary consumer's expectations, or if injury is attributable to a specific design feature of the product and the risks associated with the design outweigh its benefits. *Barker v. Lull Eng'g Co.*, 573 P.2d 443, 455-56 (Cal. 1978). The district

court concluded that Papike failed to meet either the "consumer expectation" test or the "risk-benefit" test. We find no error.

[7] Tambrands' warnings met the federal requirements and Papike's design defect claim therefore fails the "consumer expectation" test. To rule otherwise would allow the anomalous circumstance that a consumer is entitled to expect a product to perform more safely than its government-mandated warnings indicate.

The district court properly concluded that Tambrands established the benefits of their tampon's design outweighed the risks inherent in the design. We disagree with Papike's contention that in evaluating the "risk-benefit" test, the district court improperly weighed the evidence when it rejected the affidavit of Dr. Tierno, a microbiologist who has conducted tampon/TSS testing.

[8] The district court properly determined that the Tierno affidavit was insufficient to preclude summary judgment because his test results do not establish a causal connection between the composition of Tampax Original Regular tampons and TSS. As the court observed, Dr. Tierno's research in part supported Tambrands' position, because his 1985 tests detected no toxin with the Tampax Original Regular tampon (the same result he obtained with his 100 percent cotton control). Dr. Tierno's affidavit was simply insufficient to meet Papike's burden of establishing a design defect. The district court's rejection of the affidavit was not an invasion of the province of the jury, but rather part of the district court's duty to evaluate Papike's showing of the existence of some significant probative evidence. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986); *T.W. Elec. Serv., Inc. v. Pacific Elec. Contractors Ass'n*, 809 F.2d 626, 630 (9th Cir. 1987); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986).

Appendix A

VI

[9] Lastly, we consider Papike's claim that the district court erred in dismissing her remaining claims of negligence, breach of express and implied warranties, and for punitive damages. Papike alleged negligence based on inadequate warning and defective design. She does not allege negligent manufacture. The district court properly dismissed the failure to warn claims based on state and federal law. The court also properly ruled that Papike failed to meet the "consumer expectations" test for her design defect claim. The court explained that because the "consumer expectations" strict liability test is synonymous with the "reasonableness" test in negligence claims, Papike's negligent design claim must also fail. *See Barker*, 573 P.2d at 455-56 (describing the consumer expectations test). Tambrands puts it another way—that having failed to establish a design defect under *Barker*, Papike cannot meet the more "onerous evidentiary burdens" of proving *both* a design defect *and* that Tambrands acted unreasonably. *See Anderson v. Owens-Corning Fiberglas Corp.*, 810 P.2d 549, 552 (Cal. 1991). "Summary judgment may be affirmed on any ground supported by the record." *Keenan v. Allan*, 91 F.3d 1275, 1278 (9th Cir. 1996). We agree with the conclusion that Papike's negligence claims are foreclosed.

[10] The court also properly found that the legally-adequate warnings, which give notice to consumers of the possibility of contracting TSS, foreclosed Papike's claims for breach of warranty. *See Temple v. Velcro USA, Inc.*, 196 Cal. Rptr. 531, 532 (Cal. Ct. App. 1983) (adequate warning foreclosed breach of warranty action). The claim for punitive damages obviously fails as well.

VII

The judgment of the district court is affirmed.

AFFIRMED.

APPENDIX B — ORDER DENYING PLAINTIFF'S MOTION FOR RECONSIDERATION OF THE UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA FILED JANUARY 20, 1995

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

No. CV 93-5114 WJR (Sx)

KANDIS L. PAPIKE,

Plaintiff,

v.

TAMBRANDS INC.,

Defendant.

ORDER DENYING PLAINTIFF'S MOTION FOR RECONSIDERATION

On January 9, 1995, Plaintiff's Motion for Reconsideration of the Court's November 14, 1994 Ruling came on for hearing before the Court. Having considered the documentary evidence submitted, the pleadings on file, and oral argument of counsel, the Court hereby DENIES Plaintiff's Motion for Reconsideration.

Plaintiff has failed to establish sufficient grounds for reconsideration under Local Rule 7.16(c), which requires "a manifest showing of a failure to consider material facts presented to the Court before such decision." Plaintiff has not established that the Court failed to consider all of the evidence submitted on her behalf in opposition to Defendant's motion for summary

adjudication as to the design defect claim. The Court considered the evidence, including Dr. Tierno's declaration and research, and found that the absence of any material question of fact supported the granting of summary judgment in favor of Defendant.

Even assuming that Plaintiff had established sufficient grounds for reconsideration, the Court affirms its prior ruling. Under either the consumer expectation test or the risk-benefit test, the Court finds that there is no triable issue of material fact regarding whether the tampons at issue are defectively designed. *See Barker v. Lull Engineering*, 20 Cal. 3d 413, 432, 73 P.2d 443, 455-56, 143 Cal. Rptr. 225, 238 (1978) (holding that plaintiff may establish defective design using either consumer expectation test or risk-benefit test). Summary adjudication as to Plaintiff's design defect claim was properly granted in favor of Defendant. *See* Court's Ruling of November 14, 1994.

Based upon the foregoing, the Court denies Plaintiff's Motion for Reconsideration.

IT IS SO ORDERED.

DATED: January 19, 1995

s/ William J. Rea
WILLIAM J. REA
United States District Judge

APPENDIX C — TENTATIVE RULING OF THE UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA DATED JANUARY 9, 1995

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

TENTATIVE RULING

Case Number: CV 93-5114 WJR (Sx) **Docket Number:** 7

Title: *Papike v. Tambrands, Inc.*

Date: January 9, 1995

Nature of Motion: Plaintiff's Motion for Reconsideration of the Court's Ruling on the Design Defect Claim

HON. WILLIAM J. REA, JUDGE

Marva Dillard, Deputy Clerk.

TENTATIVE RULING:

The Court is inclined to DENY plaintiff's request for reconsideration of its ruling on the design defect claim.

(1) *Grounds for Reconsideration*

Local Rule 7.16(c) provides that a motion for reconsideration of the decision of any motion may be made "only on the grounds of . . . a manifest showing of a failure to

consider material facts presented to the Court before such decision."

Contrary to plaintiff's assertion, the Court carefully considered the evidence of Dr. Tierno's research in ruling upon the motion for summary judgment. The Court examined Dr. Tierno's research results, including the results from his "rabbit model" test, the *Contraception* article which discusses some of his findings, and his declarations filed in support of plaintiff's opposition. The Court found that this evidence not only failed to support the propositions advanced by plaintiff, but at times supported defendant's position. *See, e.g., Contraception* article.

Plaintiff's statement that "[t]he Court's expressed concerns regarding Dr. Tierno's research . . . actually go to the weight . . . of Dr. Tierno's testimony," and that the testimony should therefore be considered by a jury, is imprecise. Because plaintiff will bear the burden of proof at trial in establishing a design defect claim against defendant, on a motion for summary judgment, the Court must consider whether there is evidence such that a reasonable jury could return a verdict in plaintiff's favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). *Anderson*, 477 U.S. at 252.

Thus, the Court should properly consider the weight of the evidence inasmuch as plaintiff must adduce evidence such that the minimum threshold of "existence of a material question of fact" is met. *See Richards v. Neilsen Freight Lines*, 810 F.2d 898, 902 (9th Cir. 1987). The Court, in considering Dr. Tierno's declaration and the supporting evidence, found that a reasonable jury could not return a verdict for plaintiff on her design defect claim based on such evidence.

Appendix C

Plaintiff has not established that the Court failed to consider all of the evidence submitted on her behalf in opposition to defendant's motion for summary adjudication of the design defect claim. The Court considered the evidence and found that the absence of any material questions of fact supported the granting of summary judgment in favor of defendant.

(2) *Whether the Court Should Modify Its Prior Ruling*

Assuming *arguendo* that plaintiff had established sufficient grounds for reconsideration, the Court would then re-examine the merits of its ruling on the motion. Defendant moved for summary judgment as to plaintiff's design defect claim. To establish a claim for design defect, plaintiff must meet one of two alternative tests: (1) the consumer expectation test; or (2) the risk-benefit test. *Barker v. Lull Engineering*, 20 Cal. 3d 413, 432, 573 P.2d 443, 455-56, 143 Cal. Rptr. 225, 238 (1978).

(a) *Consumer expectation test*

Under the consumer expectation test, defendant is liable for a design defect if its tampons "failed to perform as safely as an ordinary consumer would expect." *Barker* at 432, 573 P.2d at 455-56, 143 Cal. Rptr. at 238. Here, the test focuses on whether an ordinary consumer would expect that the possibility of contracting TSS accompanies use of the tampons.

Given that the warnings of TSS accompanying defendant's tampons are sufficient as a matter of law, *see* Court's Ruling of August 8, 1994, consumers are presumed to have read and heeded the warning. *Carmichael v. Reitz*, 17 Cal. App. 3d 958, 990, 95 Cal. Rptr. 381, 401 (Ct. App. 1971). Based upon this

constructive knowledge, consumers know that a risk of TSS accompanies use of the tampons. As a matter of law, this defeats plaintiff's claim that the risk of TSS renders the tampon's performance below the ordinary consumer's expectations.

Plaintiff asserts that "the Court's ruling [of November 14, 1994] ignores, without comment, evidence advanced by the plaintiff demonstrating that a warning is but one aspect of an entire system" which creates consumer expectations about a product. Plaintiff adduced evidence of defendant's advertising campaign, which the Court considered in ruling upon the motion, and which plaintiff argues creates a consumer expectation that users of defendant's tampons will not contract TSS.

It is true that a warning is one of many things which create consumer expectations. However, here there is a legally-sufficient warning which informs consumers of the risk of TSS. Whatever else may influence consumer expectations, including advertising, the consumer knows (as a matter of law) that use of the defendant's tampons carries a risk of contracting TSS. In light of the constructive knowledge afforded by defendant's legally-sufficient warnings, defendant's tampons meet consumer expectations with regard to the risk of contracting TSS.

(b) *Risk-benefit test*

Under the risk-benefit test, defendant is liable for a design defect if it fails to establish that the benefits of the tampon's design clearly outweigh the risks inherent in such design. *Barker* at 432, 573 P.2d at 455-56, 143 Cal. Rptr. at 238. Plaintiff argues that the benefits of the Tampax Original Regular do not outweigh the risks associated with its use, particularly in light

of Dr. Tierno's opinion that an all-cotton tampon would be safer than defendant's current tampon.

Defendant has submitted extensive evidence regarding the widespread use of Tampax Original Regular Tampons and the relatively low incidence of TSS in its users. In short, in order for plaintiff to succeed on her claim for design defect under the risk-benefit test, a trier of fact would have to find that the most safe, most widely-used tampon on the market presents a risk of TSS that outweighs its benefits. The implication of such a finding is that tampon manufacturers would become insurers for all TSS victims, since if strict liability is imposed on the most safe design of tampons, it surely would be imposed on all other tampons.

Plaintiff states that merely "because a Tampax tampon was used to measure "relative risk" [in studies by the CDC] doesn't mean that th[e] Tampax tampon is safe for use." Motion at p. 15. Plaintiff focuses on the fact that there are risks accompanying use of defendant's tampons when she complains that the evidence does not establish that the Tampax tampon is safe for use. *Id.* Plaintiff goes on to state that, according to Dr. Tierno's experience, the CDC underreports cases of TSS.

Even considering the risks as plaintiff portrays them, these risks are greatly outweighed by the benefits associated with use of defendant's tampons. The existence of risks does not necessarily equate with a design defect; the question is one of "relative risk" as compared with the benefits. Here, because the evidence establishes that the benefits of defendant's tampons overwhelmingly outweigh the risks associated with its use, the Court is inclined to affirm its prior ruling that the tampons meet the risk-benefit test as a matter of law.

APPENDIX D — TENTATIVE RULING OF THE UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA DATED NOVEMBER 14, 1994

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

TENTATIVE RULING

Case Number: CV 93-5114 WJR (Sx) **Docket Number:** 13

Title: *Papike v. Tambrands, Inc.*

Date: November 14, 1994

Nature of Motion: Defendant's Motion for Summary Adjudication

HON. WILLIAM J. REA, JUDGE

Marva Dillard, Deputy Clerk.

TENTATIVE RULING:

The Court is inclined to GRANT defendant's motion for summary adjudication of plaintiff's design defect claim.[1] This renders moot the request for summary adjudication of the California Civil Code section 1714.45 defense.

1. As an alternative basis for the Court's ruling, the Court may also rely on the fact the plaintiff has failed to submit a Statement of Genuine Issues with her opposition papers, as required by Local Rule 7.14.2. Consequently, the Court "will assume that the material facts as claimed and adequately supported by the moving party are admitted to exist without controversy." Local Rule 7.14.3. Plaintiff's failure to submit a Statement of Genuine Issues is enough in itself to support the Court's granting of defendant's motion.

Appendix D

1. *The consumer expectation test*

Defendant is liable for a design defect under the consumer expectation test if its tampons "failed to perform as safely as an ordinary consumer would expect." *Barker v. Lull Engineering*, 20 Cal. 3d 413, 432, 573 P.2d 443, 455-56, 143 Cal. Rptr. 225, 238. In order to succeed on its motion for summary adjudication, defendant must establish that no triable fact exists as to whether its tampons met consumer expectations.

The Court has ruled that the warnings accompanying defendant's tampons are legally-sufficient warnings as a matter of law. *See* Court's ruling of August 8, 1994. Where a manufacturer supplies an adequate warning, as did the defendant here, the consumer is presumed to have read and heeded the warning. *Carmichael v. Reitz*, 17 Cal. App. 3d 958, 990, 95 Cal. Rptr. 381, 401 (Ct. App. 1971); Restatement 2d, Torts § 402A, comment j (1965).

Since consumers are on notice of the possibility of contracting TSS by virtue of the sufficient warnings accompanying defendant's tampons, consumers' expectations regarding the tampons necessarily would include an awareness of the risk of TSS. Plaintiff therefore cannot establish that the existence of this risk renders the performance of defendant's tampons below consumer expectations.

Even assuming that plaintiff had no actual knowledge of the risk, such knowledge is imputed to plaintiff by virtue of the warnings accompanying the tampons. Furthermore, an ordinary consumer, who is the measuring stick for this test, is assumed to know what is in the warning and therefore knows here that the use of tampons includes a risk of TSS. As a matter of law,

plaintiff cannot show that defendant's tampons failed to meet consumer expectations due to the risk of TSS.

2. *The risk-benefit test*

As an alternative to the consumer expectation test, defendant is liable for a design defect if defendant fails to establish that the benefits of the tampon's design outweigh the risks inherent in such design. *Barker* at 432, 573 P.2d at 455-56, 143 Cal. Rptr. at 238. If defendant can show that no question of fact exists as to whether the benefits of the tampon clearly outweigh the risks, then it is entitled to summary adjudication of that issue.

Defendant has produced competent evidence which establishes the following facts: tampons are used by millions of women around the world; tampons are the form of menstrual protection preferred by the vast majority of women; the Center for Disease Control ("CDC") has reported the incidence rate of TSS as one case per 100,000 menstruating women annually; and studies by various state agencies and the CDC have found the Tampax regular tampons used here to be the lowest risk tampon on the market. The facts all establish that the risk of contracting TSS is extremely low when compared to the benefits enjoyed by many women from use of the product

In response, plaintiff has submitted the affidavit of Dr. Tierno, who claims that his studies establish a link between the rayon and cotton composition of Tampax Original Regular tampons and TSS. However, this conclusion is not adequately supported by Dr. Tierno's research.

For example, Dr. Tierno's "rabbit model" test, which he

asserts stands for the proposition that all-cotton tampons are safer that cotton and rayon blends, actually compared cotton and rayon tampons with pure cotton fiber. Dr. Tierno's recent tests, documented in his *Contraception* article, showed no presence of toxins in the Tampax Original Regular tampons. These tests support defendant's position that the tampons at issue here are relatively safe and belie Dr. Tierno's theory that tampons made of 100% cotton would be safer.

Dr. Tierno admits that he is uncertain whether the deviations he has tracked were caused by differences in toxin production between viscose rayon and cotton, or were caused by differences in toxin recovery between the two fibers. Dr. Tierno's test results do not establish a causal connection between the composition of Tampax Original Regular tampons and TSS. Dr. Tierno's surmise to that effect is not enough to defeat defendant's motion for summary judgment.

In short, in order for plaintiff to succeed on her claim for design defect under the risk-benefit test, a trier of fact would have to find that the most safe, most widely-used tampon on the market presents a risk of TSS that is not outweighed by its benefits. The implication of such a finding is that tampon manufacturers would suddenly become insurers for all TSS victims, since if strict liability is imposed on the most safe design of tampons, it surely would be imposed on all other tampons.

Given the wide use and acceptance of tampons, such a result is unreasonable. As a matter of law, the benefits of defendant's product clearly outweigh the risk of TSS it presents to users.

APPENDIX E — TENTATIVE RULING OF THE UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA DATED AUGUST 8, 1994

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

TENTATIVE RULING

Case Number: CV 93-5114 WJR (Sx) **Docket Number:** 5

Title: *Papike v. Tambrands, Inc.*

Date: August 8, 1994

Nature of Motion: Defendant's Motion for Partial Summary Judgment

HON. WILLIAM J. REA, JUDGE

Marva Dillard, Deputy Clerk.

TENTATIVE RULING:

The Court is inclined to GRANT the motion.

1. Summary judgment standard

Summary judgment under Rule 56 of the Federal Rules of Civil Procedure is appropriate, "after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which the party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). Summary judgment may only be granted, however,

where the moving party demonstrates that there is no genuine issue of material fact and that it is entitled to judgment as a matter of law. *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157 (1970); *Richards v. Neilsen Freight Lines*, 810 F.2d 898, 902 (9th Cir. 1987).

To survive the motion, the nonmoving party need only present evidence from which a jury might return a verdict in its favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). At least some significant probative evidence tending to support the pleading must be produced. *T.W. Electrical Service v. Pacific Electrical Contractors*, 809 F.2d 626, 630 (9th Cir. 1987); *Celotex*, 477 U.S. at 324. The nonmoving party may not rest on the mere allegations of the pleadings. *Valandingham v. Bojorguez*, 866 F.2d 1135, 1142 (9th Cir. 1989). The mere existence of a scintilla of evidence in support of the respondent's position will be insufficient; there must be evidence on which the jury could reasonably find for the respondent. *Anderson*, 477 U.S. at 249, 252.

2. Failure to warn

This action is brought by plaintiff Kandis Papike to recover for injuries she allegedly sustained when she contracted Toxic Shock Syndrome ("TSS") after using defendant's Tampax brand tampons. She claims, *inter alia*, that the warnings concerning TSS that appear on the box and in a package insert contained in the box were insufficient. Defendant Tambrands contends that these "failure to warn" claims must fail as a matter of law. First, defendant argues that any state law causes of action for failure to warn are preempted by the comprehensive federal regulatory scheme covering tampons and TSS. *See* 21 U.S.C. § 360(k)(a); 21 C.F.R. § 808.1(b); 47 Fed. Reg. 26,989-90;

21 C.F.R. § 801.430. Because both the clear language of the statute and regulations at issue and the shear weight of legal authority support this position, *see, e.g., Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989); *Meyer v. Int'l Playtex, Inc.*, 724 F. Supp. 288 (D.N.J. 1988); *Parrot v. Int'l Playtex, Inc.*, No. CV 88-491 (C.D. Cal. 1989); *Platts v. Tambrands, Inc.*, No. 901712 (Cal. Super. Ct. 1991), the Court feels that Tambrands' position has considerable merit.

Defendant next argues that its warnings, which track the language of the federal regulations almost verbatim, constitute sufficient warning as a matter of law. Every court that has analyzed the specific packaging at issue in this case has found in favor of Tambrands on this issue. In addition, Tambrands provides the statements of three officials of the Food and Drug Administration ("FDA") who conclude that the Tampax packaging is in full compliance with the applicable standards. (See Letter of Eric Latish, Letter of Byron Tart, and Affidavit of Kathleen Shanahan, attached as Exhibits F-H to the Affidavit of Kimber C. Richter, M.D.). Plaintiff's evidence in opposition consists solely of the declaration of an expert in consumer behavior, Dr. Laughery, whose views have been flatly rejected by every court that has considered them, and whose comments seem to be more an attack on the FDA requirements themselves, rather than demonstrative of Tambrands' alleged non-compliance with those regulations. Such evidence is insufficient to create a material question of fact which precludes summary judgment.

For these reasons, the Court is of the opinion that defendant's motion for partial summary judgment — seeking dismissal of all of plaintiff's claims which are premised on failure to warn — should be granted in its entirety.

APPENDIX F — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT FILED APRIL 16, 1997

NOT FOR PUBLICATION
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 95-55173
D.C. No. CV-93-05114-WJR(Sx)

KANDIS L. PAPIKE,

Plaintiff-Appellant,

v.

TAMBRANDS INC.,

Defendant-Appellee.

ORDER

Before: O'SCANNLAIN, T.G. NELSON and HAWKINS, Circuit Judges.

The panel has voted to deny appellant's petition for rehearing and to reject the suggestion for rehearing en banc.

The full court has been advised of the suggestion for rehearing en banc and no judge of the court has requested a vote on whether to rehear the matter en banc. Fed. R. App. P. 35.

The petition for rehearing is denied and the suggestion for rehearing en banc is rejected.